



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/203,004 02/28/94 BERD

D 1225/00674

DARBY & DARBY PC  
805 THIRD AVENUE  
NEW YORK NY 10022

HM22/1129

EXAMINER

UNGAR, S

ART UNIT	PAPER NUMBER
----------	--------------

1642

44

DATE MAILED:

11/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/203,004

Applicant(s)

Berd

Examiner  
Ungar

Group Art Unit  
1642



☒ Responsive to communication(s) filed on Sep 27, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 43, 44, 47, 49-62, 64-72, and 74-77 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 43, 44, 47, 49-62, 64-72, and 74-77 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

1. The Amendment filed September 27, 2000 (Paper No. 43) in response to the Office Action of March 22, 2000 (Paper No. 41) is acknowledged and has been entered. Previously pending claims 54, 55, 57, 66 and 70 have been amended. Claims 43, 44, 47 and 49-62, 64-72 and 74-77 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

***Claim Rejections - 35 USC § 112***

4. Claims 43, 49-51, 54-55 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 41, Section 10, pages 7-8.

Applicant argues that the composition is a useful component of a vaccine and that the specification enables a haptized tumor cell composition in combination with an adjuvant and that for that reason both components must be enabled.

Applicant further cites case law to demonstrate that products are useful if they serve as starting materials in producing other materials which are directly useful and therefore Examiner errs in interpreting these claims as requiring adjuvant. The argument has been considered but has not been found persuasive because the claims are not drawn to a component of a vaccine that upon addition of an adjuvant will elicit an immune response but rather specifically recite the limitation that upon injection the composition (without adjuvant) elicits an inflammatory immune response. For the reasons previously set forth, without an adjuvant the claim is not enabled. Applicant's arguments have not been found persuasive and the rejection is maintained.

Art Unit: 1642

***Claim Rejections - 35 USC § 103***

5. Claims 47 and 65-72 and 74-77 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 36, Section 10, pages 8-12 and in Paper No. 41, Section 5, pages 2 and 3.

Applicant argues (a) in order for a combination of prior art references to suggest a claimed invention, an objective teaching must exist in the prior art that would lead a skilled artisan to combine its teaching; (b) it is impermissible to use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention, (c) Applicant takes issue with Examiner's contention that Applicant has argued and discussed the references individually without clearly addressing the combined teachings since each reference must be considered in its entirety and then evaluation must be made as to whether the reference can be properly combined with the others and whether the combination suggests the claimed invention with a reasonable expectation of success (d) Applicant discusses the individual references, (e) Applicant reiterates the arguments drawn to the rejection of claims 47 and 65-76 in Paper No. 36, Section 10, pages 8-12.

The arguments have been considered but have not been found persuasive (a') for the reasons previously set forth in Paper No. 51 on page 3, it is suggested that Applicant review *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981), (b') Some degree of hindsight is permissible in making rejections under 35 USC 103 since it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But, so long as it takes

Art Unit: 1642

into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It is clear that a method for treating melanoma comprising sensitizing with DNCB, administering a therapeutically effective amount of cyclophosphamide and administering a therapeutically effective amount of autologous, irradiated DNP-conjugated melanoma cells mixed with BCG was well known in the art as taught by Murphy et al and that immunization schedules wherein antigen is administered on a schedule of at least six times at spaced intervals was conventional in the art as taught by the Antibody Patents cited on Page 10 of Paper No. 36 and that a dose of 300 mg/M<sup>2</sup> was successfully administered prior to autologous irradiated, DNP-conjugated melanoma cells as taught by Berd et al and the equivalence of halogenated dinitrobenzenes for the elicitation of delayed hypersensitivity was known in the art as taught by Geczy et al. Given the information known in the art, the combined references teach not only the suggestion but also the means and motivation to successfully treat a malignant tumor in a human patient as claimed, (c') upon review and reconsideration it is found that, in Examiner's view, Applicant did not clearly address the combined teachings of the references, (d') and (e') Applicant's arguments are not persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

Art Unit: 1642

6. Claims 47 and 65-72 and 74-77 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 36, Section 11, pages 12-15 and in Paper No. 41, Section 6, page 4.

Applicant argues that for the reasons set forth above the rejection is in error and should be withdrawn. The argument has been considered but is not found persuasive for the reasons set forth above. Applicant's arguments have not been found persuasive and the rejection is maintained.

7. Claims 43, 44, 47 and 49-62, 64-72 and 74-77 remain rejected for the reasons previously set forth in Paper No. 36, Section 12, pages 15-18 and in Paper No. 41, Section 7, pages 4-5.

Applicant argues that (a) it is not expected that vaccines using other types of tumor cells would behave in a mechanistically similar manner to the melanoma vaccine described in Berd et al since Hanna et al teaches a method for treatment of human colon cancer using a vaccine made from irradiated human tumor cells and Hoover teaches that when comparing vaccines made from irradiated autologous cells of colon cancer patients and rectal cancer patients, only the colon cancer patients received benefit from the vaccine, (b) Applicant again argues that Wiseman does not supply the missing teaching and the "preliminary" nature of the results of Berd et al.

The arguments have been considered but have not been found persuasive because (a') Wiseman clearly showed that autologous irradiated melanoma, lung, colon and kidney cancer cells were successfully used for successful immunological treatment of those cancers and it would have been expected that these cell types,

Art Unit: 1642

already known in the art to be useful as immunogenic cancer treatments would be successfully substituted for the melanoma cells of Berd et al in order to treat the other cancer types. The fact that a single cancer cell type is not immunogenic is not relevant in view of the demonstrated efficacy of the cell types of Wiseman, (b') the arguments are not persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

8. Claims 43, 44, 47 and 49-62, 64-72 and 74-77 remain rejected for the reasons previously set forth in Paper No. 36, Section 13, pages 18-21 and in Paper No. 41, Section 8, page 6.

Applicant argues that Berd '83 does not provide an incentive to prepare a haptenized tumor cell vaccine or methods of treating cancer using said vaccine. The argument has been noted but has not been found persuasive for the reasons previously set forth. Applicant is arguing this reference individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Art Unit: 1642

9. Claims 43, 44, 47 and 49-62, 64-72 and 74-77 remain rejected for the reasons previously set forth in Paper No. 36, Section 14, pages 21-25 and in Paper No. 41, Section 9, page 7.

Applicant reiterates the arguments previously set forth. The arguments have been considered but have not been found persuasive for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

10. All other objections and rejections recited in Paper No. 41 are withdrawn.

11. No claims allowed.

12 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is




Art Unit: 1642

(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

  
Susan Ungar  
Primary Patent Examiner  
November 28, 2000